

Attorney Docket No.: DEX-0150  
Inventors: Sun et al.  
Serial No.: 09/762,021  
Filing Date: August 6, 2001  
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#### REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Claim 1 has been amended. Support for the amendments is provided throughout the specification for example at page 1, lines 4-7, page 3, lines 3-6, page 4, line 2, page 6, lines 4-15, page 7, lines 15-22 and page 13, lines 15-18. No new matter is added by this amendment. Reconsideration of the rejection of claim 1 is respectfully requested in light of the amendments and the following remarks.

#### I. Rejection of Claim 1 under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claim 1 under 35 U.S.C. § 112, first paragraph.

Arguments presented by Applicants in the response filed January 23, 2004 were not found convincing.

In particular, the Examiner suggests that arguments presented that a skilled clinician could distinguish between HSV infection and colon cancer based upon other factors is not persuasive because this limitation is not recited in the claims.

Thus, while Applicants respectfully disagree with the Examiner that the alignments provided demonstrate in any

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way shared epitopes between HSV and the encoded protein of SEQ ID NO:1, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to include language that the patient is suspected of having colon cancer. Support for this amendment is provided in teachings throughout the specification, for example at page 4, line 2, page 7, lines 15-22 and page 13, lines 15-18.

Further, in response to the Examiner's invitation to point to the column and line of U.S. Patent 5,733,748 which establishes that for colon specific genes a correlation would be expected between polynucleotide and polypeptide, Applicants respectfully direct the Examiner to col. 2, line 36-42 where it is taught that an aspect of the present is to provide "a method and products for diagnosing colon cancer metastases by detecting an altered level of a polypeptide corresponding to the colon specific genes of the presence invention . . . " Further at col. 8, lines 16-19 it is taught that "it is detection of this enhanced transcription or enhanced protein expression in cells, other than those derived from the colon, which is indicative of metastasis of colon cancer.

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U.S. Patent 5,861,494 (provided as reference AB in the IDS submitted by Applicants on February 1, 2001) also teaches that altered levels of polypeptide corresponding to a colon specific gene indicated a colon cancer diagnosis. See specifically col. 2, lines 31-37. Also see col. 8, lines 10-13 wherein it is taught that "elevated levels of the colon specific polypeptides of the present invention, indicates active transcription and expression of the corresponding colon specific gene product."

These teachings, which are specific to colon specific genes and polypeptides encoded thereby are clearly far more representative of what is believed by those skilled in this art field than references cited by the Examiner relating to the anomalies of ferritin, ornithine decarboxylase, p-glycoprotein and p53.

Thus, since the more relevant prior art is indicative of a correlation between polynucleotide and encoded polypeptide levels of colon specific genes, the teachings of the instant specification relating to this aspect would not be questioned by the skilled artisan.

Finally, with respect to the Examiner's question regarding the protein being a cell surface receptor or secreted into the bodily fluid, it is respectfully pointed

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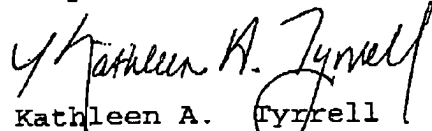
out that the claimed invention for detecting the presence of colon cancer is not dependent on the subcellular location of the protein. Further, successful detection methods have been developed for cell surface receptor proteins as well as secreted proteins. Thus, there is no reason for one of skill to doubt the teachings of the instant specification regarding successful use of the claimed method for detecting the presence of colon cancer.

Withdrawal of this rejection is therefore respectfully requested.

## II. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Communication of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

Date: November 23, 2004

LICATA & TYRRELL P.C.  
66 E. Main Street  
Marlton, New Jersey 08053  
(856) 810-1515